DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 17 2012

Re: HALAVEN
Docket No.: FDA-2011-E-0156

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the application for patent term extension for U.S. Patent No. 6,214,865, filed by Eisai R&D Management Co., Ltd., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for HALAVEN (eribulin mesylate), the human drug product claimed by the patent.

The total length of the regulatory review period for HALAVEN (eribulin mesylate) is 2,758 days. Of this time, 2,527 days occurred during the testing phase and 231 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: April 30, 2003.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 30, 2003.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: March 30, 2010.

   FDA has verified the applicant's claim that the new drug application (NDA) for HALAVEN (NDA 201-532) was submitted on March 30, 2010.

3. The date the application was approved: November 15, 2010.

   FDA has verified the applicant's claim that NDA 201-532 was approved on November 15, 2010.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Paul J. Berman/Christoher N. Sipes
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